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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,574	08/05/2003	Ramin Shiekhattar	WSTR-0014C	1505

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EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,574	SHIEKHATTAR, RAMIN	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-3,7-12 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-6 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of V (claims 4-6 and 13) in the reply filed on 10/20/2006 is acknowledged. The traversal is on the ground(s) that there would not be an undue burden placed on the examiner to search elected group V with non-elected groups I and II, because the search for methods of group V would reveal art related to the subjects of groups I and II. This is not found persuasive because the search for group V is broadly for the active steps of the claimed methods. Furthermore, the scope of the claimed methods in group V is very broad and encompasses methods that do not necessarily involve BRCC36 or BRE, which are required in the group I or group II. Also, the active steps of the methods encompassed group V encompass monitoring cellular events (such as response to irradiation or expression of p53 response element containing proteins) that do not necessarily involve expression or activity of BRCC36, BRE or other BRCC components.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-17 are pending. Claims 1-3, 7-12 and 14-17, drawn to non-elected claims, are withdrawn from consideration.

Claims 4-6 and 13 are examined on the merits.

Claim Rejections - 35 USC § 112

3. Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 are indefinite in the recitation of BRCC, because at one point in the specification BRCC appears to be defined at page 5 of the specification as containing 10 elements, whereas at page 17, the specification appears to define BRCC as containing at least 2 elements from a list of proteins.

4. Claims 4-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is that the term BRCC is not adequate described by the specification, and since the claimed methods require contacting BRCC or cells containing BRCC with test agents, the claimed methods are not adequately described.

At page 17 of the specification, assays that contain BRCC are defined as assays that include two or more BRCC components from a list that of components that include but *are not limited to* BRCA2, BRCA1, RAD51, BRCC300, BRCC140, BRCC130, BRCA1 Δ11, BRCC80, BRE, BRCC36, and BARD1 (emphasis added). Because the specification appears to define BRCC as comprising components that are not included in the list on page 17, the scope of BRCC includes protein complexes, as well as protein compositions comprising at least two components

selected from an incomplete list. Therefore, the term BRCC appears to represent a genus of protein complexes or a genus of compositions comprising two or more components, where not all of the components of the complex or composition are characterized.

For a claim drawn to a genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative number of species" means that the species, which are adequately described, are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus (see Official Gazette 1241 OG 174, January 30, 2001).

In the instant case, the specification describes experiments that show that BRCC is made up of 10 components, whereas the claims broadly encompass assays using BRCC, where the BRCC is made up of two or more components, where possibly the two or more components are not yet defined. Therefore, the specification fails to provide a representative number of species of BRCC, because the one species that is defined is one made up of 10 defined components, whereas the claims encompass species comprised of undefined components.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Li (Li, L. et al., Biochemical and Biophysical Research Communications, 206(2): 764-774, 1995).

Claim 13 is drawn to a method for identifying an agent that inhibits the expression of BRCC36 or BRE protein comprising contacting a cell expressing BRCC36 or BRE protein with a test agent and monitoring the ability of the agent to alter the expression of BRCC36 or BRE protein. The specification describes the screening assays of the present invention directed to screening for agents that decrease expression of BRCC36 or BRE as assays that include methods such as northern blot analysis, reverse transcriptase PCR. Therefore, claim 13 appears to read on methods where mRNA levels are measured as an indication of gene expression.

Li teaches methods of detecting changes in BRE gene expression by UV irradiation and differentiating agents (see pages 767-770) in cells expressing BRE. Therefore, Li teaches a method that is the same as that claimed.

6. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Silverman (US 6,331,396; issue Dec. 18, 2001).

Please note that for claim 13, provisional applications 60/401,433 60/449,950 do not disclose a method comprising contacting a cell expressing BRE protein. Therefore, the effective filing date for this claim is that of the instant application, 8/05/2003.

Claim 13 is drawn to a method for identifying an agent that inhibits the expression of BRCC36 or BRE protein comprising contacting a cell expressing BRCC36 or BRE protein with a test agent and monitoring the ability of the agent to alter the expression of BRCC36 or BRE protein. The specification describes the screening assays of the present invention directed to screening for agents that decrease expression of BRCC36 or BRE as assays that include methods such as northern blot analysis, reverse transcriptase PCR. Therefore, claim 13 appears to read on methods where mRNA levels are measured as an indication of gene expression.

Silverman teaches methods of detecting changes in BRCC36 (also known as c6.1A) gene expression due to interferon-alpha, -beta or –gamma (see abstract and Table 4, columns 83 and 84 GenBank Accession No. X64643). Silverman teaches that the methods include measurement of mRNA expression or of protein expression (see column 2, line 35 – column 3, line7). Therefore, Silverman teaches methods that are the same as that claimed.

7. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Hashizume (Hashizume, R. et al., The Journal of Biological Chemistry, 276 (18): 14537-14540, 2001, May; cited in the IDS).

Claim 4 is drawn to a method for identifying an agent that modulates the ubiquitin E3 ligase activity or ubiquitin hydrolase activity of BRCC comprising contacting BRCC with a test agent and monitoring the ability of said agent to alter the level of ubiquitination of select protein which is indicative of ubiquitin E3 ligase activity or ubiquitin hydrolase activity of BRCC. The specification appears to teach that an assay containing BRCC is one that contains two or more components, such as, for example, BRCA1 and BARD1 (see page 17, lines 7-14).

Hashizume teaches exposing a BRCA1 and BARD1 to E2F1, cyclin B1, and CstF50 and testing for an effect on ubiquitin E3 ligase activity (see page 4538, 2nd column). Therefore, Hashizume teaches a method that is the same as that claimed.

8. Claim 4 is rejected under 35 U.S.C. 102(a) as being anticipated by Mallery (Mallery, D.L. et al. The EMBO Journal, 21(24): 6755-6762, 2002, Dec.).

Please note that for claim 4, provisional applications 60/401,433 60/449,950 do not disclose a method for identifying an agent that modulates ubiquitin hydrolase activity of BRCC. Therefore, the effective filing date for this claim is that of the instant application, 8/05/2003.

Mallery teaches a method comprising exposing BRCA1/BARD1 to BAP1 (an ubiquitin hydrolase) to test for deubiquitylation of a polyubiquitylated form of BRCA1/BARD1. Therefore, Mallery teaches a method that is the same as that claimed.

9. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Preisler (Preisler, V.K. et al. Cancer Letters, 145: 29-33, 1999) as evidenced by Vissac (Vissac, C. et al. Clinical Chimica Acta, 320: 101-110, 2002).

Preisler teaches a method for identifying an agent that alters DNA repair in MCF-7 cells (see page 30). Vissac provides evidence that MCF-7 cells express BRCA1 and BRCA2. Therefore, Preisler teaches a method of identifying an agent that modulates DNA repair activity of BRCC comprising contacting BRCC with a test agent and monitoring the ability of the agent to alter cell survival rates.

10. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Pradier (Pradier, O. et al, J. Cancer Res. Clin. Oncol. 125: 20-27, 1999) as evidenced by Vissac (Vissac, C. et al. Clinical Chimica Acta, 320: 101-110, 2002).

Pradier teaches a method for identifying an agent that alters radiation sensitivity in MCF-7 cells (see page 30). Vissac provides evidence that MCF-7 cells express BRCA1 and BRCA2. Therefore, Pradier teaches a method of identifying an agent that modulates DNA repair activity of BRCC comprising contacting BRCC with a test agent and monitoring the ability of the agent to alter cell survival rates.

11. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Blagosklonny (Blagosklonny, M.V., et al. Cancer Res. 55(20): 4623-4626, 1995) as evidenced by Vissac (Vissac, C. et al. Clinical Chimica Acta, 320: 101-110, 2002) and also as evidenced by Saramaki (Saramaki, A. et al., Nucleic Acids Research, 34(2): 543-554, 2006).

Blagosklonny teaches a method for identifying an agent that alters the expression level of p21WAF1, which as evidenced by Saramki, is encoded by a gene that contains a p53 response element (see abstract). Blagosklonny teaches the method in MCF-7 cells, which are cells that

express BCRA1 and BCRA2, as evidenced by Vissac. Therefore, Blagosklonny teaches a method of identifying an agent that modulates the transcriptional regulator activity of BRCC comprising contacting a cell containing BRCC with a test agent and monitoring the ability of the agent to alter expression of a gene containing a p53 response element.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
January 5, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER